

EXHIBIT E

January 7, 2013

Page 1

SUPERIOR COURT OF NEW JERSEY
ATLANTIC COUNTY/CIVIL DIVISION
DOCKET NO. ATL-L-6966-10

- - -
LINDA GROSS and JEFFREY GROSS, :STENOGRAPHIC
Plaintiffs, :TRANSCRIPT OF:
:
v. :
:
: - HEARING -
GYNECARE, ETHICON, INC., JOHNSON & :
JOHNSON, and JOHN DOES 1-20, :
Defendants. :

- - -
PLACE: ATLANTIC COUNTY COURTHOUSE
1201 Bacharach Boulevard
Atlantic City, New Jersey

DATE: January 7, 2013
- - -

B E F O R E:

THE HONORABLE CAROL E. HIGBEE, P.J. Cv.

- - -
ANN MARIE MITCHELL, CCR, RDR, CRR
GOLKOW TECHNOLOGIES, INC.
877.370.3377 ph| 917.951.5672 fax
deps@golkow.com

GOLKOW TECHNOLOGIES, INC. - 877.370.3377

January 7, 2013

Page 105

1 difficult to decide specifically how you draw the
2 line, but we do know that, you know, overall, that's
3 not an appropriate approach.

4 THE COURT: To each of these experts
5 that you've named, you can prepare an order that
6 indicates that the motion to exclude their testimony
7 is denied at this time, that the -- without
8 prejudice to the defense to object to any particular
9 line of questioning at the time of trial, and that
10 the witnesses are precluded from making inflammatory
11 or judgmental statements about the corporation
12 and/or from stating their own belief as to what the
13 company's personal interpretation or intent was.

14 But they can certainly lay it out. They can
15 certainly define certain words and terms and things
16 like that, if it's a medical point of view or if
17 it's, you know, something about a particular
18 proceeding, they could put it in context.

19 So I really think we have to
20 basically play it question by question at the time
21 of trial. But counsel should make sure that its
22 witnesses understand that both -- you know, when
23 they were doing this, they were really trying to do
24 XYZ or they were really trying to hide this or --
25 you know, that as interpretations are not

January 7, 2013

Page 106

1 appropriate. And we've already really ruled on
2 that. I think I already said about intent
3 previously in another motion.

4 So that and inflammatory statements
5 about their -- this shows how evil they are or, you
6 know, they were bad actors, or this shows how greedy
7 they are, anything like that shouldn't be part of an
8 expert's testimony.

9 MR. SLATER: Understood.

10 THE COURT: So having said that, give
11 those instructions to your experts. And then if
12 there's a particular question that you feel is
13 outside their expertise or a document that you think
14 the questioning is inappropriate about, we'll just
15 have to deal with it on a step-by-step basis.

16 MR. ANDERSON: Your Honor, if I
17 could, please. There's a slight difference between
18 Dr. Klinge and Ms. Pence and Dr. Weber in that he
19 was an Ethicon consultant and, therefore, he has
20 expert testimony, also has fact testimony, because
21 he worked with them to develop surgical meshes for
22 greater than ten years. And so there may be some
23 subtle differences there we need to consider when he
24 is testifying. I just wanted to raise that to Your
25 Honor's attention.

January 7, 2013

Page 107

1 THE COURT: No, I agree.

2 MR. ANDERSON: Thank you.

3 THE COURT: I still don't think he
4 probably would be somebody you would want to use --
5 we don't still want inflammatory language.

6 MR. ANDERSON: Correct.

7 THE COURT: But when it talks about
8 intent, if he's saying I conferred with the company
9 officials and this is why we did this, then I think
10 that that would obviously be an exception.

11 MR. ANDERSON: Thank you.

12 THE COURT: Then he's talking about
13 what his intent was and their intent when they were
14 dealing with him as to what he specifically said,
15 but that will be allowed.

16 MR. SLATER: One other small
17 question.

18 These motions that have been filed
19 before Dr. Shott was videotaped for trial, and I
20 carefully cautioned her and she was very -- stayed
21 away from all of it. In fact, her testimony was so
22 narrow that the defense lawyer had to take some time
23 to recast the cross because I stayed away from
24 everything.

25 The one thing I just wanted to flag

January 17, 2013

Page 1270

SUPERIOR COURT OF NEW JERSEY
ATLANTIC COUNTY/CIVIL DIVISION
DOCKET NO. ATL-L-6966-10
- - -

LINDA GROSS and JEFFREY GROSS,
Plaintiffs,

v.

GYNECARE, ETHICON, INC., JOHNSON &
JOHNSON, and JOHN DOES 1-20,
Defendants.

:STENOGRAPHIC
:TRANSCRIPT OF:
:
:
: - TRIAL -
:
:
:

- - -
PLACE: ATLANTIC COUNTY COURTHOUSE
1201 Bacharach Boulevard
Atlantic City, New Jersey

DATE: January 17, 2013
- - -

B E F O R E:

THE HONORABLE CAROL E. HIGBEE, P.J. Cv.

- - -

ANN MARIE MITCHELL, CCR, RDR, CRR
GOLKOW TECHNOLOGIES, INC.
877.370.3377 ph| 917.951.5672 fax
deps@golkow.com

GOLKOW TECHNOLOGIES, INC. - 877.370.3377

January 17, 2013

Page 1314

1 involved in the evaluation of the raw data collected in
2 a clinical trial to evaluate the safety and efficacy of
3 a medical device; am I correct?

4 A Correct.

5 MS. JONES: Your Honor, that's all I have.
6 I do have an objection.

7 THE COURT: Okay. Want to come to sidebar?

8 - - -

9 (The following occurred at sidebar:)

10 MS. JONES: Oh.

11 THE COURT: Do you have another question
12 for her?

13 MS. JONES: I thought about it. I'll wait.
14 That's all right.

15 Your Honor, counsel tendered Dr. Weber as
16 an expert in several areas. I do object to her
17 testimony with respect to anything regarding the
18 regulatory aspects of Prolift, the FDA regulations and
19 whether or not the device complied with the regulations
20 and whether or not Ethicon complied with the
21 regulations. I also object on the basis of lack of
22 qualifications to anything relating to the internal
23 design process, compliance with the internal design
24 process, the conduct of that design process by Ethicon.

25 I further object to the testimony with

January 17, 2013

Page 1315

1 respect to polypropylene, the biomaterials aspects of
2 the case, including the porosity of mesh, anything
3 relating to the pathology of mesh. It's on the basis
4 of lack of qualification for her to testify in this
5 area.

6 Now, let me be candid. This witness has
7 submitted about 600 pages worth of reports in here, and
8 I'm not sure that Mr. Slater is actually tendering her
9 as an expert in all of those areas, but I do object to
10 any regulatory testimony. I object to any testimony
11 with respect to the design defect -- device design
12 safety analysis, the FMEA or all of those for total
13 lack of experience.

14 MR. SLATER: I'll take them one at a time.

15 With regard to FDA regulations, she's not
16 going to offer any FDA regulatory opinions. In her
17 testimony she may talk about her familiarity with what
18 was going on with the company. And all of her
19 testimony is going to be couched within the
20 decision-making and the input that would have been or
21 should have been provided by the medical affairs people
22 in the company.

23 As Your Honor has started to see in this
24 case, and I'll give you a regulatory example, one of
25 the criteria that Sean O'Bryan admitted would have

January 17, 2013

Page 1316

1 required him to seek 510(k) clearance would have been
2 if medical affairs had said that clinical study was
3 needed in order to establish substantial equivalence or
4 other criteria for the 510(k) process. She's certainly
5 qualified to give all those opinions.

6 The person in medical affairs who was
7 responsible to make all of these decisions when the
8 Prolift went on the market was four years out of her
9 residency with no fellowship training, had worked at
10 three general gynecologic clinics in Florida, had never
11 operated on her own with mesh, she had participated in
12 surgeries where she basically assisted another surgeon
13 who used some mesh a few times with some of her
14 patients, this is Charlotte Owens, and that was the
15 person who then made all of the medical affairs
16 decisions related to the Prolift, including the
17 decision that it was safe and effective and could be
18 placed on the market. She gave all of the input to
19 regulatory affairs they relied on in making their
20 decision not to seek FDA 510(k) clearance.

21 I'll talk about the design assessments.
22 Dr. Weber has intimate knowledge of the process. She
23 is not going to provide an opinion that the process
24 itself was either good or bad, but what she will do is
25 provide the testimony that Piet Hinoul has agreed would

January 17, 2013

Page 1317

1 come within the purview of medical affairs.

2 I will give you the two prime examples.

3 Number one, the DDSA and FMEA was required to address
4 all potential hazards and harms or adverse events that
5 could occur to a woman through the use of the Prolift.
6 The person in the company who was responsible to make
7 sure that that was done was Charlotte Owens of medical
8 affairs.

9 THE COURT: One second.

10 - - -

11 (The sidebar ended.)

12 - - -

13 THE COURT: We'll take a short break and
14 let the jury take a break.

15 (The jury leaves the courtroom.)

16 - - -

17 (The following occurred at sidebar:)

18 MR. SLATER: Charlotte Owens in medical
19 affairs was the person in the company required and
20 relied on to advise and make sure that all of the
21 potential risks were going to be evaluated. And Piet
22 Hinoul said, if that wasn't done, the process was
23 flawed. Dr. Weber will have opinions that Charlotte
24 Owens failed to make sure that all of the potential
25 risks were evaluated, because she's been through the

January 17, 2013

Page 1318

1 documents. She understands how to read them. She
2 understands the process -- she's read every single
3 deposition in this case. She's read every document.
4 And she's not going to provide an opinion that DDSA is
5 a good or a bad thing, the FMEA is a good or a bad
6 thing, but what she's going to say is, Charlotte Owens'
7 role was to do this.

8 She's certainly qualified to offer opinions
9 about whether or not a gynecologist with training and
10 experience that's a small fraction of Dr. Weber's,
11 whether or not she captured what was needed to be
12 captured based on the standards the company followed.

13 I'll give you another example. Well, I
14 mean, that was I think the things that were
15 specifically addressed.

16 With regard to polypropylene mesh, Dr.
17 Weber is the co-author of an ACOG practice bulletin
18 that was published in February of 2007, Clinical
19 Management Guidelines for the Treatment of Pelvic Organ
20 Prolapse, in which an analysis was provided of the
21 emerging polypropylene mesh technology -- the emerging
22 polypropylene mesh technology. She's named on the
23 cover of the ACOG practice bulletin, along with another
24 urogynecologist, Scott Smilen. They made
25 recommendations to all gynecologists in the United

January 17, 2013

Page 1319

1 States who are members of ACOG in this practice
2 bulletin and drew certain conclusions, including this:

3 "When choosing the best material for
4 specific procedures, it is critically important that
5 surgeons understand how certain characteristics of
6 materials play a key role in the risk/benefit ratio for
7 various types of surgery. Pore size in surgical mesh
8 is one of the most important factors determining risk
9 of postoperative infection."

10 I'm just reading some quotes from this.

11 Another part of it.

12 "Although several studies have evaluated
13 anterior colporrhaphy with and without mesh or graft
14 materials of different types, because of heterogeneity
15 of materials studied, small sample sizes and short-term
16 follow-up, it is not possible to draw definitive
17 conclusions about the risk versus the benefit of
18 absorbable or permanent synthetic materials in anterior
19 colporrhaphy."

20 "Given the limited data and frequent
21 changes in the marketed products, particularly with
22 regard to type of mesh material itself, which is most
23 closely associated with several of the postoperative
24 risks, especially mesh erosion, the procedures should
25 be considered experimental and patients should consent

January 17, 2013

Page 1320

1 to surgery with that understanding."

2 She is the person who is recognized on the
3 cover of this practice bulletin. It says, and I'll
4 give the specific cite for the record, this is Clinical
5 Management Guidelines for Obstetrician & Gynecologists,
6 ACOG practice bulletin number 79, February 2007, volume
7 109, number 2, part 1.

8 "This practice bulletin was developed by
9 the ACOG committee on practice bulletins, gynecology
10 with the assistance of Scott W. Smilen, MD and Anne M.
11 Weber, MD, MS. The information is designed to aid
12 practitioners in making decisions about appropriate
13 obstetric and gynecologic care."

14 That's in part what it says.

15 So she has been instrumental in looking
16 into this field. Practice bulletins, as Your Honor I'm
17 sure is aware, in ACOG are given a lot of respect and a
18 lot of importance. They're read, they're looked at.
19 So Dr. Weber certainly has the ability to comment on
20 anything within the company that medical affairs was
21 involved in, because that is the field that she is in.
22 Certainly no one is disputing her expertise in that.

23 Again, Charlotte Owens was the person who
24 made all of the critical medical decisions within the
25 company that were relied on by regulatory, quality

January 17, 2013

Page 1321

1 engineering, marketing, a whole host of issues. Every
2 major issue in this case, it ended up on Charlotte
3 Owens' desk. And Dr. Owens' testimony, she certainly
4 can testify to her understanding of the processes and
5 then focus her opinions down.

6 I was talking about design control before.
7 Number one, her opinion is they did not come close to
8 evaluating all of the potential risks and adverse
9 events that could have resulted from the Prolift.
10 Chapter and verse. And she has more than enough
11 qualification to give those opinions, because Charlotte
12 Owens was the one who signed off.

13 Number two, the clinical expert report,
14 which we've been through in this trial now, she
15 absolutely is qualified to talk about the inadequacy of
16 that clinical expert report as an evaluation of the
17 available clinical evidence at the time and whether or
18 not that clinical evidence provides a favorable
19 risk/benefit ratio such that the Prolift should have
20 been cleared by Charlotte Owens of medical affairs to
21 go to PRA and be marketed. Her opinions will be
22 couched within her expertise and within her profession
23 and her specialization.

24 When it comes to study design, nobody is
25 going to argue with her qualifications. She started

January 17, 2013

Page 1322

1 the area in the NIH to fund NIH studies of
2 urogynecologic surgery and disorders. She is more than
3 qualified to comment on the clinical studies that were
4 performed. If counsel wants to say it goes to the
5 weight, because she hadn't personally done a study of
6 the Prolift or of mesh, hey, have at it. I think it's
7 going to be more than apparent to the jury that her
8 expertise, which was brought to this and reading
9 hundreds and hundreds of thousands of pages of internal
10 documents, reading every single deposition in this case
11 by every person involved, reading a pile of medical
12 literature that is astounding, she has spent over 2,000
13 hours working on this case. That's more than 83
14 consecutive days. And they're going to put on experts
15 who haven't looked at any of these materials.

16 So she has more than adequate basis and
17 more than adequate -- and we're talking about now about
18 her expertise, but any opinion -- and, again, medical
19 affairs, clinical study and design, that is exactly
20 what she is.

21 THE COURT: Well, it appears to me that
22 you've addressed any concerns raised about her ability
23 to testify about everything that happened within the
24 company as far as their studies, whether they were
25 adequate, inadequate. She's obviously a specialist in

January 17, 2013

Page 1323

1 designing studies and evaluating, and she has the
2 educational background and the ability to do that. The
3 fact that she herself has not designed a product, those
4 all go to the weight of her testimony.

5 The only area that I'm concerned about is
6 the regulatory and the 510(k) approval and -- because
7 she really doesn't see --

8 MR. SLATER: I'll tell you what -- I'm
9 sorry to interrupt, because I know time is valuable.

10 THE COURT: Let us know what we're going to
11 do with that.

12 MR. SLATER: This is what she's going to
13 say. She is not going to provide an opinion that they
14 needed to get 510(k) clearance. Okay? That's Dr.
15 Pence, who is going to testify next week.

16 But there's two areas that she is more than
17 qualified and a few areas that relate to that.

18 Number one, the question of whether or not
19 Gynemesh and the Prolift are essentially the same
20 thing. She's certainly qualified to talk about the
21 differences from a clinical standpoint in terms of the
22 surgical procedures, in terms of how this would
23 interact with the body, in terms of the -- now you're
24 taking -- she can certainly differentiate them, not in
25 a regulatory standpoint, but from a medical surgical

January 17, 2013

Page 1324

1 standpoint, what a surgeon would think when looking at
2 these and say what's the same, what's different. And
3 that's one thing.

4 THE COURT: She's someone who is an expert
5 in surgical procedures, and I have no problem with her
6 testifying to the difference in the surgeries between
7 the two, whether she's performed them or not, and in
8 the difference in the -- well, the difference in the
9 procedures, the difference in the complications, the
10 difference in the way they're performed, the
11 differences in between the materials themselves, that
12 she would be qualified to do.

13 When it gets into did this -- what is
14 510(k), how would -- do you intend to address the FDA
15 with her?

16 MR. SLATER: The only way that I intend to
17 address that question is this. She's aware of the
18 regulatory status. It's a fact in the case. There's
19 documents and there's testimony that establishes what
20 happened at what time. I will ask her, does she have
21 an opinion as to whether or not a reasonable
22 urogynecologist, gynecologist or urologist, what they
23 would have done if they knew the facts. Would it be
24 significant to a surgeon to know that a product or a
25 system, the Prolift, was or was not cleared if that was

January 17, 2013

Page 1325

1 necessary. I'm going to ask her to assume certain
2 facts and say, assuming those facts, do you have an
3 opinion as to whether a reasonable surgeon in this
4 field would or would not use any medical device knowing
5 that. And, in fact, she doesn't have to only rely on
6 something in the abstract, she has the testimony of Dr.
7 Benson, the implanting surgeon, who says I wouldn't
8 have used it. She has the testimony of Vincent
9 Lucente, their US investigator, their most important
10 key opinion leader, says, I wouldn't have used it, I
11 didn't know. David Robinson, their medical affairs
12 director, who says, I would have had to take a close
13 look at it, who while he was an investigator and then
14 was using the product after launch, never knew it
15 didn't have clearance.

16 So she has facts to rely on from multiple
17 people who were employed by the company. Axel Arnaud
18 parenthetically found out last year it wasn't cleared.

19 So she has the absolute ability to give
20 that opinion of what a surgeon in this field would or
21 would not have thought was significant in whether to do
22 a surgical procedure. She has more than enough of a
23 foundation for it. And she's not going to give an
24 opinion as to whether or not 510(k) clearance was
25 needed or not. Not her field, not going to ask the

January 17, 2013

Page 1326

1 question.

2 MS. JONES: That is absolutely irrelevant
3 in this case. What's important in this case is what
4 Dr. Benson testified to, period. And she -- what any
5 reasonable surgeon other than Dr. Benson --

6 MR. SLATER: Then I ask for a directed
7 verdict on failure to warn and deceit right now. I'd
8 like a directed verdict. If counsel says the only
9 thing that matters is what Dr. Benson said, his trial
10 testimony is locked in stone now, he said he wouldn't
11 have used it. Therefore, I ask for a directed verdict.

12 MS. JONES: That is -- Your Honor, his
13 testimony will come in at the appropriate time in the
14 appropriate manner when Your Honor rules.

15 Now, the --

16 THE COURT: Well, the argument as to
17 whether it was, quote, experimental to a degree or
18 whether it was in fact simply an extension of a prior
19 procedure that had been done, I think first -- I think
20 that clearly falls within her expertise as a surgeon
21 who's performed numerous different types of surgery and
22 who specialized in the type of repairs that we're
23 talking about, so I'm going to allow her to do that.

24 As to whether what a reasonable surgeon
25 would do if advised, I think that is part of it and is

January 17, 2013

Page 1327

1 appropriate. Obviously, the jury is going to give
2 great weight, I'm sure, to what Dr. Benson said, but in
3 evaluating the credibility of Dr. Benson and evaluating
4 the statements that were made by him, I think that part
5 of her expertise goes to what surgeons would have
6 understood, would not have understood, what they would
7 have wanted to know, why they would have wanted to know
8 it. She's coming at it from the point of view of a
9 surgeon. I'm going to allow her to give that
10 testimony.

11 All right. We'll proceed. And if there's
12 any objections to any particular questions, you can
13 make them, obviously. And the objection to her
14 speaking about the regulatory process is -- I'm
15 sustaining that objection as far as the process itself,
16 as far as what the process is, what the 510(k)
17 requires, what -- whether they did or did not comply.
18 Counsel's indicated she's not going to be asked about
19 that, and so the regulatory process, I think, which she
20 has limited qualification in, I grant that motion.

21 The motion as to the design of the product
22 itself and whether a surgeon would have been able to
23 work with it and how it would affect, I'm going to
24 allow. All right.

25

- - -